

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) An assay device to determine the presence of at least one analyte of interest in a liquid sample, the device comprising a test strip on which is deposited:
a first latex-labeled analyte-specific binding reagent for generating a first signal, or 'test' signal, which indicates the presence and/or amount of analyte of interest in the sample; and
~~at least 16.5 micrograms of~~ a second latex-labeled specific binding reagent from a control latex suspension having a latex concentration of at least 1.5% w/v for generating a second signal, the generation of which second signal indicates both
 - (a) the test has been successfully conducted, and that
 - (b) sufficient time has elapsed following contact of the assay device with the liquid sample for the test to be read and the first signal to have been properly generated.
2. (Currently amended) The device of claim 1, wherein the analyte of interest is hCG.
3. (Previously presented) The device of claim 1, wherein the device is a lateral flow immunochromatographic assay device.
4. (Cancelled)
5. (Currently amended) The device of claim 1, wherein the second signal has a signal development time of is-generated about 1 minute ~~after the device is contacted with the sample~~.
6. (Previously presented) The device of claim 1, wherein the second signal is a visible signal which appears in a portion of the test device covered by a layer of translucent material.
7. (Previously presented) The device of claim 1, wherein the second signal has a signal development time of less than 10 seconds.

8. (Previously presented) The device of claim 7, wherein the second signal has a signal development time of less than 8 seconds.

9. (Cancelled)

10. (Previously presented) A method of performing an assay to determine the presence of an analyte of interest in a sample, the method comprising the steps of: contacting an assay device according to claim 1 with the sample; observing the appearance of the second signal; observing the appearance of the first signal when the second signal has appeared; and concluding that the analyte of interest is present in the sample if the first signal appears when the second signal has appeared.

11. (Previously presented) The method of claim 10, wherein the sample is a sample of body fluid.

12. (Previously presented) The method of claim 11, wherein the sample is urine.

13. (Previously presented) The method of claim 10, wherein the analyte of interest is hCG.

14. (Previously presented) The device of claim 1, wherein the sufficient time is a pre-determined time.

15. (Previously presented) The device of claim 1, wherein the second latex-labeled specific binding reagent is deposited on the test strip at a position more than 16.5 mm measured from a position at which the liquid sample is to be applied to the test strip.

16. (Previously presented) The device of claim 15, wherein the second latex-labeled specific binding reagent is deposited on the test strip at a position less than or equal to 25 mm measured from a position at which the liquid sample is to be applied to the test strip.

17. (Previously presented) The device of claim 1, wherein the second latex-labeled specific binding reagent is deposited on the test strip at a position less than or equal to 25 mm measured from a position at which the liquid sample is to be contacted to the test strip.

18. (Previously presented) The device of claim 1, further comprising a laminate placed over the deposit of second latex-labeled specific binding reagent.

19. (Previously presented) The device of claim 18, wherein the laminate comprises a translucent laminate.

20. (Previously presented) The device of claim 1, wherein the device comprises up to about 22 micrograms of second latex-labeled specific binding reagent.

21. (Previously presented) The device of claim 1, wherein the first latex-labeled analyte-specific binding reagent comprises a first antibody specific for the at least one analyte of interest.

22. (Previously presented) The device of claim 21, wherein the second latex-labeled specific binding reagent comprises a second antibody specific for a third antibody that is specific for the at least one analyte of interest.

23. (Previously presented) The device of claim 1, wherein the test strip has a capillary flow time of about 180 seconds per 4 centimeters.

24. (Previously presented) A method of making the device of claim 1, comprising:
depositing the first latex-labeled analyte-specific binding reagent on the test strip; and
depositing the second latex-labeled specific binding reagent on the test strip from a control latex suspension having a latex concentration in the range of about 1.5% to 2% w/v.